OBJECTIVES: A multi-centre, prospective, observational study aimed to recruit 500 newly diagnosed AF patients and 500 matched controls to assess AF symptom burden and HRQOL using THIN UK primary care data. Patient enrolment as soon after diagnosis as possible was vital. Existing methodology of identifying patients from fully processed data would not have enrolled patients as quickly as necessary to assess newly diagnosed AF. The objective was to assess the effectiveness of a novel methodology used to recruit patients as soon after diagnosis as possible from THIN. **METHODS:** Cases and controls matched by age, gender and geography were identified as soon as data were received from THIN practices rather than after data were fully processed (normal route for identifying patients). Patients were therefore identified within one week of diagnosis being recorded. Practices were contacted by THIN staff and asked to confirm eligibility. Practices invited eligible patients to participate, ensuring no direct contact between THIN staff and patients. Patients were asked to complete HRQOL questionnaires at enrolment, 6 and 12 months' follow-up. **RESULTS:** Within 18 months, this method was successful in recruiting beyond the necessary sample size (516 case-control pairs). This methodology minimised the impact of recruitment and follow-up on clinical management of patients, who were seen at a frequency determined in accordance with their normal medical care only. Diagnostic assessments of patients were not required and so, other than the questionnaires, there was no additional burden to normal clinical practice. **CONCLUSIONS:** This is an innovative method for patient recruitment using THIN primary care patient data. Newly diagnosed AF patients who might be eligible and for whom clinical information is already available can be quickly identified. Large numbers of newly diagnosed patients can be recruited more rapidly compared to existing methods and followed up in an efficient and cost-effective way.

PRM180

HOW PERSONALIZED SHOULD WE BE? A SYSTEMATIC REVIEW OF TAILORED & TARGETED HEALTH COMMUNICATION INTERVENTIONS TO IMPROVE ADHERENCE

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OBJECTIVES: To target patients with "personalized" interventions with the highest probability of success, understanding what works with other behaviors provides empirical guidance, as few outcomes are explicitly medication adherence-related. This study's purpose is to glean 1) the characteristics of individuals or interventions examined in "tailored" or "targeted" health communication interventions, and 2) the components or combination of successful strategies tailored to the individual's needs and targeted to the social groups in which the patient is embedded. **METHODS:** A systematic review was conducted, with articles identified via searches in MEDLINE and Embase, using keywords representing individual, interventional, and behavioral factors. Inclusion criteria: published peer-reviewed articles in English, 2000-2012; 77 studies reflected behavioral outcomes (medication adherence, preventive screening, health promotion, and self-management of disease). The review specified individual factors (sociodemographic, behavioral, contextual, disease) as well as elements upon which interventions were customized (delivery, content, form, dose/frequency, setting, level of analysis). **RESULTS:** Across all outcomes assessed (n=133), 52.6% of tailored or targeted interventions demonstrated statistically significant benefit, with additional 12.8% effective (not statistically), 9.8% mixed, 24.8% non-significant. Regarding behaviors associated with multiple morbidities: most studies evidenced health promoting effects (medication adherence, 66.7%; diet/obesity, 65.9%; physical activity, 47.4%; screening, 71.4%). Disease-specific outcomes reflected stronger findings. Individual characteristics were clustered into groups for analysis, with significantly positive effects for 3 of 4 clusters: sociodemographic, 59.0%; behavioral, 63.4%, contextual, 52.6%. Within group differences indicated support for specific factors within each cluster (age vs. education, barriers vs. self-efficacy). Effects were moderated by intervention-type (tailored vs tailored+targeted). **CONCLUSIONS:** A matrix developed for this review permits a refined approach to creating interventions focusing on the interaction ("person x intervention") features of effective strategies. Several candidate characteristics of patients to prioritize in medication adherence program development were identified, using evidenced-based selection of patient-centered strategies that appropriately match what has worked and for whom.

PRM181

DEVELOPMENT OF A NEW PATIENT REPORTED OUTCOME (PRO) MEASURE FOR ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI)

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OBJECTIVES: We describe the process and progress of the Foundation for the NIH Biomarkers Consortium Project Team, a public-private partnership of government, academia, non-profit, and industry. The goal is development and qualification of a new ABSSSI PRO instrument incorporating reliable, well-defined and relevant endpoints for patients in terms of how they feel and function in clinical trials of antibacterial drugs for ABSSSI. **METHODS:** We adhered to the U.S. Food and Drug Administration (FDA) PRO Guidance for instrument development (2009) and the 2010 FDA qualification process for drug development tools (DDTs). This guidance describes the process for DDTs intended for use in multiple drug development programs, the goal of the current effort. Once qualified, drug developers can use DDTs for the qualified context in Investigational New Drug (IND) and New Drug Application (NDA)/Biological License Application (BLA) submissions without FDA reconsideration of the DDTs suitability. **RESULTS:** The initial phase of instrument development included a literature review and gap analysis (see Cimms et al., 2013 ISPOR abstracts) and interviews with 9 clinical experts. The most commonly reported symptoms were pain and tenderness across all ABSSSI subtypes- cellulitis (n=8), wound infection (n=7), and abscess (n=7). These efforts led to the development of a study protocol and interview guide to elicit concepts from ABSSSI patients. Following qualitative analysis of the interview transcripts, the team will draft a PRO instrument based on key concepts identified from ABSSSI patients and experts. The draft PRO will be evaluated by an expert panel and refined through cognitive debriefing interviews with patients. **CONCLUSIONS:** A consortium-based approach was useful and efficient in developing a new draft PRO measure for ABSSSI, which incorporates published literature and data from qualitative interviews. The team is planning a similar approach for development of a draft clinician reported outcome for ABSSSI and a CABP PRO.

PRM182

METHODOLOGICAL CHALLENGES IN MAPPING A DISEASE SPECIFIC PSYCHOMETRIC INSTRUMENT TO A DISEASE SPECIFIC UTILITY INSTRUMENT: THE EFFECT OF ALTERNATE UTILITY TRANSFORMATIONS AND WITHIN-INSTRUMENT SUB-SCALE CORRELATIONS ON MODEL FIT

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OBJECTIVES: a) Determine the effect of utility transformations on the fit of linear regression used to map psychometric disease-specific instrument scores to disease-specific utility scores and b) determine whether the model fit is dependent upon the correlation between the disease specific and non-specific items of the preference-based instrument. **METHODS:** We compare regression models mapping scores from the UCLA Prostate Cancer Index (PCI), a psychometric instrument measuring Health Related Quality of Life for prostate cancer patients, to utility responses from PORPUS-U, a prostate cancer-specific utility instrument with disease-specific and generic subscales. Models were fitted using a dataset from prostate cancer patients, while fit was assessed on three separate datasets, using the Root Mean Squared Error (RMSE) in the retransformed scale. The often poor fit of regression-based mapping models may be due to limited overlap between the constructs addressed by preference-based and psychometric instruments. We investigated this hypothesis employing a simulation procedure where we: a) fitted a multivariate regression model estimating how the generic subscales depend on the disease-specific ones, b) used these estimates, with varying noise, to simulate generic subscale scores, c) calculated utility scores from the true disease-specific and simulated generic subscales, d) applied linear regression to map PCI scales to "semi"-simulated PORPUS-U utilities, and f) evaluated the mapping using RMSE, determining whether a "tighter" correlation structure improves the fit. **RESULTS:** The arcsin transformation appears to give the best fit, with RMSE values of 0.0405, 0.0605 and 0.0457 for the three test datasets. The simulation experiments showed that larger correlation between disease specific and non-disease specific instrument domains only yields a marginal benefit in the mapping. **CONCLUSIONS:** Transforming utility scores does affect model fit, and appears to be an important step in utility mapping. Limited construct overlap between disease-specific and generic items in prostate cancer quality of life instruments did not evidently explain suboptimal fit in our mapping models.

PRM183

THE EFFECT OF INCLUDING AN OPT-OUT OPTION IN DISCRETE CHOICE EXPERIMENTS

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OBJECTIVES: To study to what extent an opt-out option in a Discrete Choice Experiment (DCE) influences the attribute estimates and the conclusions drawn from the DCE. **METHODS:** A questionnaire was sent to 2,500 Dutch Diabetes Mellitus Type 2 (DM2) patients, each questionnaire contained 9 choice tasks with and 9 without an opt-out alternative. Panel-mixed-logit models were used to estimate the relative importance of the five attributes included (menu schedule, physical activity (PA) schedule, consult structure, expected outcome and out-of-pocket costs). It was empirically tested whether the relative importance of the attributes differed between a DCE with or without opt-out alternative. Additionally, it was tested whether results differed between respondents that were offered the opt-out option in the first 9 choice tasks and those who could choose to opt-out only in the second 9 choice tasks. **RESULTS:** In both datasets (with and without opt-out), consult structure (β=-0.54, β=-0.53), expected outcome (β=0.64, β=0.77) and out-of-pocket costs (β=-0.79, β=-0.67) showed significant attribute estimates (P<.001). However, the relative importance of these attributes differed between both datasets. The frequency of choosing to opt-out was higher among participants that first had this option, compared to respondents that were first forced to make a choice. The regression analyses on these subgroups showed different results with respect to the elaborate PA schedule (β=0.10; P>.05 versus β=0.13; P<.05). **CONCLUSIONS:** Conclusions drawn